5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

DEC - 4 2009

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Jizhong Jin Regulatory Affairs Specialist
Phone Number:	(651) 733-6655
FAX Number:	(651) 737-5320

Date of Summary: October 7, 2009

Device Name and Classification:

Common or Usual Name:	Sterilization process indicator
Proprietary Name:	3M™ Comply™ Bowie-Dick Type Lead Free Test Pack
Classification Name:	Indicator, Physical/Chemical Sterilization Process (21 CFR § 880.2800(b))
Performance Standards:	N/A

Predicate Device:

3M™ Comply™ 1233 Bowie-Dick Type Test Pack (ATI Bowie-Dick Test Pack)

Description of Device:

The 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack is equivalent in performance to the Bowie-Dick towel pack described in AAMI ST79. The test pack consists of a chemical indicator test sheet positioned within a pack of porous sheets. The test sheet contains a lead-free steam-sensitive chemical indicator ink printed on paper as a yellow-colored pattern. The test sheet will turn a uniform dark brown/black color except when air removal failures such as air leaks occur. An air removal failure is indicated by a lighter-colored area in the indicator ink pattern of an otherwise dark-colored test sheet.

Indications for Use:

The 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack is designed for testing air removal efficiency of 132- 134°C (270- 273°F) dynamic-air-removal steam sterilizers.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this Special 510(k) submission shows that the 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack is substantially equivalent to the predicate device 3M™ Comply™ 1233 Bowie-Dick Type Test Pack (ATI Bowie-Dick Test Pack), cleared under K841168 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 4 2009

Mr. Jizhong Jin
Regulatory Affairs Specialist
3M Company
3M Center, Building 275-5W-06
Saint Paul, Minnesota 55133-3275

Re: K093199
Trade/Device Name: 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 10, 2009
Received: November 13, 2009

Dear Mr. Jin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K093199

Device Name: 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack

Indications For Use:

The 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack is designed for testing air removal efficiency of 132- 134°C (270- 273°F) dynamic-air-removal steam sterilizers.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth A. Claverie - W

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K093199